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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

JANSSEN, SHANNON L

ART UNIT

PAPER NUMBER

1639

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/593,908	Applicant(s) SUN ET AL.	
	Examiner SHANNON JANSSEN	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 10-25 is/are pending in the application.
- 4a) Of the above claim(s) 10-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :September 15, 2009 and November 11, 2009.

DETAILED ACTION

Claims 1-25 are pending. Claims 10-25 have been withdrawn. Claims 1 and 5 were amended and claims 6-9 were cancelled in the amendments received November 11, 2009. Claims 1-5 are under consideration.

Election/Restrictions

Applicant's elected Group I, claims 1-9, **without** traverse in the reply filed on July 7, 2009.

Claims 10-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on application number 200410029590.7 filed in China on March 26, 2004. Acknowledgment is made that applicants have filed a certified English translation of the foreign priority document. The present application is a national phase entry of PCT/CN2005/000387 filed March 28, 2005.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on September 15, 2009 and November 11, 2009 are being considered by the examiner.

Withdrawn Objections

The objection to claims 5 and 6 are withdrawn in view of the claim amendments.

Withdrawn Rejections

The rejection of claims 7-8 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the claim amendments.

The rejection of claims 1-3, 5-7, and 9 under 35 U.S.C. 102(a) as being anticipated by Du et al. (Development of miniaturized competitive immunoassays on a protein chip as a screening tool for drugs, 2005, Clinical Chemistry, vol 51, pp 368-375, published online Nov 24, 2004, provided by applicants in IDS) alone or as evidenced by O'Neil et al. (The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals (14th Edition - Version 14.3). Merck & Co., Inc. accessed online and downloaded from http://www.knovel.com/web/portal/browse/display?_EXT_KNOVEL_DISPLAY_bookid=1863&VerticalID=0; downloaded on 7/27/09) regarding the molecular weight of the compounds utilized by Du et al. is withdrawn in view of the claim amendments and the certified copy of the foreign priority document.

The rejection of claims 1-7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Knecht et al. (Automated microarray system for the simultaneous detection of antibiotics in milk, 2004, Analytical Chemistry, vol 76, pp 646-654, published Feb 1, 2004, provided by applicants in IDS), alone or as evidenced by O'Neil et al. (The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals (14th Edition - Version 14.3). Merck & Co., Inc., accessed online and downloaded from http://www.knovel.com/web/portal/browse/display?_EXT_KNOVEL_DISPLAY_bookid=1863

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&VerticalID=0; downloaded on 7/27/09) regarding the molecular weights of the compounds utilized by Knecht et al. is withdrawn in view of the claim amendments.

The rejection of claims 1-9 under 35 U.S.C. 103(a) as being unpatentable over Knecht et al. (Automated microarray system for the simultaneous detection of antibiotics in milk, 2004, Analytical Chemistry, vol 76, pp 646-654, published Feb 1, 2004, provided by applicants in IDS) as evidence by O'Neil et al. (The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals (14th Edition - Version 14.3). Merck & Co., Inc., accessed online and downloaded from

http://www.knovel.com/web/portal/browse/display?_EXT_KNOVEL_DISPLAY_bookid=1863 &VerticalID=0; downloaded on 7/27/09) regarding the molecular weights of the compounds utilized by Knecht et al. and in view of Ellis et al. (Interactions of CD80 and CD86 with CD28 and CTLA4, 1996, The Journal of Immunology, vol 56, pp 2700-2709) is withdrawn in view of the claim amendments.

The rejection of claims 1-9 under 35 U.S.C. 103(a) as being unpatentable over Knecht et al. (Automated microarray system for the simultaneous detection of antibiotics in milk, 2004, Analytical Chemistry, vol 76, pp 646-654, published Feb 1, 2004, provided by applicants in IDS) as evidence by O'Neil et al. (The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals (14th Edition - Version 14.3). Merck & Co., Inc., accessed online and downloaded from

http://www.knovel.com/web/portal/browse/display?_EXT_KNOVEL_DISPLAY_bookid=1863 &VerticalID=0; downloaded on 7/27/09) regarding the molecular weights of the compounds

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utilized by Knecht et al. and in view of Li et al. (WO 04/099440, filed May 9, 2003, designating the US) is withdrawn in view of the claim amendments.

New Rejections Necessitated by Amendments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The present claims are drawn, briefly, to a biochip comprising a solid support and a conjugate of a carrier and a small molecule compound immobilized on the surface.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knecht et al. (Automated microarray system for the simultaneous detection of antibiotics in milk, 2004, Analytical Chemistry, vol 76, pp 646-654, published Feb 1, 2004, provided by applicants in IDS) as evidence by O'Neil et al. (The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals (14th Edition - Version 14.3). Merck & Co., Inc., accessed online and downloaded from

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http://www.knovel.com/web/portal/browse/display?_EXT_KNOVEL_DISPLAY_bookid=1863&VerticalID=0; downloaded on 7/27/09) regarding the molecular weights of the compounds utilized by Knecht et al., and Vetro et al. (Development of a sensitive ELISA for the determination of Fumonisin B1 in cereals, 2000, Journal of Agricultural and Food Chemistry, Vol 48, pp 2821-2825).

For present **claim 1**, Knecht et al. teach an array (ie: biochip) comprising a glass solid support (p 649, col 1, para 3) and a conjugate of a carrier, such as OVA, and a small molecule compound (p 648, col 2, para 2) immobilized on the surface of the solid support (p 649, col 2, para 3, abstract).

For present **claim 2**, Knecht et al. do not disclose a particular size, however, the small molecules taught (See Tables 1,2) are known in the art to have molecular weights between 1 and 10000 daltons. For example, the molecular weight of streptomycin is less than 600 g/mol (ie: daltons), as evidenced by O'Neil et al. (see http://www.knovel.com/web/portal/browse/display?_EXT_KNOVEL_DISPLAY_bookid=1863&VerticalID=0; under the heading monographs; streptomycin, downloaded on 7/27/09).

For present **claim 3**, Knecht et al. teach a two dimensional array (Fig. 3).

For present **claim 4**, Knecht et al. teach small molecules such as sulfamethazine, streptomycin, and neomycin (throughout, see Tables 1, 2, 3).

For present **claim 5**, Knecht et al. teach the small molecule gentamycin (see Tables 1, 2, 3).

While Knecht et al. teach a microarray useful for screening a sample (such as milk) for the presence of small molecules, Knecht et al. do not specifically teach a carrier comprising HAS, BSA, or KLH.

For present **claim 1**, Vetro et al. teach an array for the detection of a small molecule toxin in a sample (such as a food sample) comprising a conjugate of BSA and the small molecule compound immobilized on the solid support (see p 2822). Vetro et al. further teach the small molecule compound also conjugated to KLH and state, regarding the small molecule, "it's coupling to different carrier proteins [OVA, BSA, HSA, KLH, or cholera toxin (CT)] ...is very easy)" (see p 2823, col 1, last paragraph).

Therefore it would have been obvious to one skilled in the art at the time of the invention to utilize one of the carriers taught by Vetro et al. in the array taught by Knecht et al.

One would have been motivated to do this because Vetro et al. teach that any of the carriers, such as OVA, BSA, HAS, and KLH, can be used and further teach that they can be changed in order to improve results (see p 2823, col 2, para 2).

One would have had a reasonable expectation of success because both Knecht et al. and Vetro et al. teach successfully coupling small molecules to carriers on an array, and further teach successful detection of small molecules using the array.

In addition, it would have been obvious to one of skill in the art at the time of the invention to substitute one known element (ie: the carriers such as OVA, HAS, BSA, and KLH as taught by Vetro et al.) for another known element (i.e.: the carriers such as OVA and GOx as taught by Knecht et al.) because it would have yielded predictable result of an array with a

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conjugate of a small molecule and a carrier. See *KSR International Co. v. Teleflex Inc.*, USPQ2d 1385 (U.S. 2007).

Therefore, the teachings of Knecht et al. and Vetro et al. render the claims to be *prima facie* obvious.

Response to Arguments

Applicant's arguments with respect to claims 1-5 have been considered but are moot in view of the new ground(s) of rejection. In addition, Knecht et al. do teach BSA conjugates for gentamicin and neomycin(see p 648).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Future Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANNON JANSSEN whose telephone number is (571)270-1303. The examiner can normally be reached on Monday-Friday 9:00AM-6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/
Primary Examiner, Art Unit 1639

Shannon L Janssen
SLJ